

NOV 10 2003

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: \_\_\_\_\_.

1. Submitter's Identifications:

Meditek Technology Inc.  
1F, No. 11, Lane 223, Sec. 3, Chung Ching N. Rd.,  
Taipei, Taiwan, R.O.C.

Contact:  
Mr. Rodin Chang  
President

Date of Summary Preparation: September 25, 2002.

2. Name of the Device:

Meditek Blood pressure Monitor, model M100.

3. Information of the 510(k) Cleared Device (Predicate Device):

Health care: HL-168(K990807).

4. Device Description:

The Meditek Blood Pressure Monitor, model M100, is the non-invasive electronic medical device intended for the measuring of blood pressure (including systolic pressure and diastolic pressure) and the number of heart beats of patient by using the oscillometric method. According to the general principle of the oscillometric method, the cuff was placed on patient's wrist or arm. The cuff was inflated by using pneumatic pump to the estimated pressure and then was deflated at a certain deflation rate. During the deflation of pressure, the pressure and its oscillation was measured. The measuring pressure and its oscillation are calculated and analysed by the software of the microprocessor according to the algorithm of oscillometric method.

After completing the measuring cycle, the systolic pressure, diastolic pressure, and heart beat rate are displayed on the LCD of device. All the measuring information and the time of measuring may be stored in the memories of device. Those stored memories may be transmitted out of device through the signal transmission cable.

Basically the blood pressure monitor M100 is the device measuring blood pressure at wrist.

5. Intended Use:

The M100 Blood Pressure Monitor is an electric device that provides a signal from which the systolic, diastolic, and rate of heart beats can be derived through the use of transducers placed on the surface of body. The signals of measurement can be stored in the memory of device, and then can be displayed on the screen of device and/or be transmitted out of device by using the standard signal transmission cable.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The cleared device for the specification comparison of M100 is HL-168 (K990807).

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, SP 10-1992, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

8. Conclusions

The Meditek Blood Pressure Monitor, including model M100, has the same intended use and technological characteristics as the cleared device of HL-168. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Meditek Technology, Inc.  
c/o Mr. Tony C. S. Chang  
Official Correspondent  
1F, No. 11, Lane 223, Sec. 3  
Chung Ching N. Road  
Taipei  
Taiwan, R.O.C.

Re: K032308

Trade Name: Blood Pressure Monitor, Model M100  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Monitor  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: November 3, 2003  
Received: November 3, 2003

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

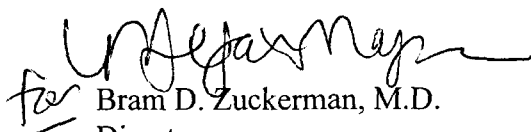
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Tony C. S. Chang

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

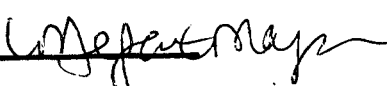
510(k) Number (if known): \_\_\_\_\_

Device Name: Blood Pressure Monitor / M100**Indications For Use:**

The M100 of blood pressure monitor is an electronic device that provides a signal from which the systolic, diastolic and rate of heart beats can be derived through the use of transducers placed on the surface of the body. The signals of measurement can be stored in the memory of device, and then can be displayed on the screen of device and/or be transmitted out of device by using the standard signal transmission cable.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K032308   
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number \_\_\_\_\_

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒